FDA 510(k) Premarket Notification

K200749 CUBEScan BioCon-900S

CLEARED

May 19, 2020
57 days to decision

K200749 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k200749/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 23, 2020
Decision date	May 19, 2020
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mcube Technology Co., Ltd.**
Location	Flintville, TN, US
Contact	Hye-Ri Choi
510(k) history	6 submissions · 6 cleared · 2009-2020